DEC 1 0 2002

K 022284

510 (k) Summary

June 21, 2002

William A. Belfer, DMD, MSc.D
Dental Imagineers, LLC
804 West Park Avenue
Ocean, New Jersey 07712

Phone: (732) 493-4747
Fax: (732) 493-4742

Device/Trade Name: Snore-Aid® Max

Descriptive Name: Mandibular Advancement and Tongue Positioning Orthotic (MAPTO)

Common Name: Anti-snoring Device

Classification Name: Device, Anti-snoring

Substantial Equivalence Devices: The Snore-Aid® Max appliance is substantially equivalent to its predicate Snore-Aid® Plus device (K 991449), Quiet Knight (K962516), and Snore Guard (K882303) devices.

Snore-Aid® Plus is a single plate mandibular advancement and tongue positioning orthotic consisting of an occlusal bite plate, an external maxillary lip shield, and a wide occlusal surface. The primary function of the Snore-Aid® Max is to open the pharyngeal airway by mandibular advancement and tongue positioning in order to reduce snoring and obstructive sleep apnea

Intended Use: Snore-Aid® Max is prescribed for the patient by the healthcare professional.

A. Snore-Aid® Max is indicated for use in patients with benign snoring, or snoring and mild to moderate obstructive sleep apnea (OSA) where mandibular advancement and tongue positioning can increase pharyngeal air space.

B. Snore-Aid® Max is indicated to prevent symptoms of nocturnal parfunctional jaw activity in patients who are undergoing treatment for snoring and/or OSA by mandibular advancement and tongue positioning.

Technological Characteristics: Quiet Knight is a dual plate appliances in which the upper and lower plates are connected by an adjustable hook and screw assembly that holds the mandible in an advanced position. Adjustments are made by turning the screw with a special wrench until the advancement is 70% of the maximum protrusion. Quiet knight uses unique material polycaprolactone instead of EVA to form the retentive portion of the appliance. With Snore Guard the mandibular advancement takes place by having the patient bite into the softened EVA material in an edge toe edge position. With both the predicate and the Snore-Aid® Max the adjustment is effected by poisoning the lip shield rearwardly in successive increments until the appliance reduces snoring and OSA. The Snore-Aid® Max is a hybrid appliance that may utilize the external lip shield or it may utilize an internal lip shield. In the latter case, the lip shield must be applied against a thin vacuum formed tray to protect the gingival tissue and adsorb pressure across the maxillary arch. The value of both methods is that there is no hinge required in the appliance. Also, the design of Snore-Aid® Max facilitates a simple and inexpensive chair side process using polycaprolactone to mold and customize the body of the appliance.

Clinical Data: See section on performance

Conclusion: The Snore-Aid® Max is appropriate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2002

Mr. William A. Belfer
Dental Imagineers, LLC
804 West Park Avenue
Ocean, New Jersey 07712

Re: K022284
Trade/Device Name: Snore-Aid® Max
Regulation Number: None
Regulation Name: Anti-Snoring Device
Regulatory Class: Unclassified
Product Code: LRK
Dated: October 9, 2002
Received: October 7, 2002

Dear Mr. Belfer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 022284

510(k) Number (if known): _____

Device Name: Snore-Aid® Max

Indications For Use:

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A. Snore-Aid® Max is indicated for use in patients with benign snoring or snoring and mild to moderate obstructive sleep apnea (OSA) where mandibular advancement and tongue positioning can increase pharyngeal air space.

B. Snore-Aid® Max is indicated to prevent symptoms of nocturnal parafunctional jaw activity in patients who are undergoing treatment for snoring and/or OSA by mandibular advancement and tongue positioning.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K022284